

Version 1.1 Revision Date 11-18-2013 Print Date 03-18-2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : SYMPHONY N2+ CLEAN 1

Mat.-No./ Genisys-No. : 05279569001

Manufacturer or supplier's details

Company : Roche Diagnostics Limited

Charles Avenue

Address : Burgess Hill

RH15 9RY West Sussex

Telephone : +44 1444 256000 Telefax : +44 1444 256239

Emergency telephone : +49(0)621-759-2012 oder +49(0)621-759-4848 oder

number +49(0)8856-60-2629

Emergency telephone number:

In case of emergencies: : Health, Safety & +44 1444 256500 or +44 7802

(Roche Diagnostics Ltd.) Environment 260498

- +44 1444 256561 or +44 7710

Product Safety / Vigilance 391653

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 Toxicology 24Hr help-line:
 : NPIS:
 +44 844 892 0111

 Health Advice 24Hr help-line:
 NHS Direct:
 +44 845 4647

NHS 24: +44 8454 242424

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

Emergency Overview

Physical state	liquid
Colour	colourless
Odour	vinegar-like

GHS Classification

Skin corrosion : Category 1A Serious eye damage : Category 1

GHS Label element

Hazard pictograms

E B

Signal word : Danger



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Hazard statements : H314 Causes severe skin burns and eye damage.

Precautionary statements : **Prevention**:

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P301 + P330 + P331 IF SWALLOWED: rinse mouth. Do NOT

induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/

shower.

P304 + P340 IF INHALED: Remove victim to fresh air and keep

at rest in a position comfortable for breathing.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/

physician.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Potential Health Effects

Carcinogenicity:

IARC No component of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

ACGIH No component of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential

carcinogen by ACGIH.

OSHA No component of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential

carcinogen by OSHA.

NTP No component of this product present at levels greater than or

equal to 0.1% is identified as a known or anticipated carcinogen

by NTP.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Preparation

Hazardous components

Chemical Name	CAS-No.	Concentration [%]
acetic acid	64-19-7	>= 5 - < 10

SECTION 4. FIRST AID MEASURES



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General advice : Move out of dangerous area.

Consult a physician.

Show this safety data sheet to the doctor in attendance.

Do not leave the victim unattended.

If inhaled : Move to fresh air.

Move to fresh air.

If unconscious place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

In case of skin contact : Immediate medical treatment is necessary as untreated

wounds from corrosion of the skin heal slowly and with

difficulty.

If on skin, rinse well with water. If on clothes, remove clothes.

In case of eye contact : Small amounts splashed into eyes can cause irreversible

tissue damage and blindness.

In the case of contact with eyes, rinse immediately with plenty

of water and seek medical advice.

Continue rinsing eyes during transport to hospital.

Remove contact lenses. Protect unharmed eye.

Keep eye wide open while rinsing.

If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.

Keep respiratory tract clear. Do NOT induce vomiting.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician. Take victim immediately to hospital.

Rinse mouth with water.

Notes to physician : The first aid procedure should be established in consultation

with the doctor responsible for industrial medicine.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

: High volume water jet

Specific hazards during

firefighting

: Do not allow run-off from fire fighting to enter drains or water

courses.

Further information : Collect contaminated fire extinguishing water separately. This

must not be discharged into drains.

Fire residues and contaminated fire extinguishing water must

be disposed of in accordance with local regulations.



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Special protective equipment

for firefighters

: Wear self contained breathing apparatus for fire fighting if

necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.

Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Prevent product from entering drains.

Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

: Soak up with inert absorbent material (e.g. sand, silica gel,

acid binder, universal binder, sawdust).

Keep in suitable, closed containers for disposal.

Use neutralizing agents.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Do not breathe vapours/dust.

Avoid contact with skin and eyes. For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

Dispose of rinse water in accordance with local and national

regulations.

To prevent leaks or spillages from spreading, provide a

suitable liquid retention system.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated

place.

Observe label precautions.

Electrical installations / working materials must comply with

the technological safety standards.

Materials to avoid : Keep away from oxidising agents, strongly alkaline and

strongly acid materials in order to avoid exothermic reactions.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
acetic acid	64-19-7	TWA	10 ppm	ACGIH
		STEL	15 ppm	ACGIH
		TWA	10 ppm 25 mg/m3	NIOSH REL



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ST	15 ppm 37 mg/m3	NIOSH REL
TWA	10 ppm 25 mg/m3	OSHA Z-1
TWA	10 ppm 25 mg/m3	OSHA P0

Personal protective equipment

Hand protection

Material : Protective gloves

Remarks : The selected protective gloves have to satisfy the

specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be

discussed with the producers of the protective gloves.

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Wear face-shield and protective suit for abnormal processing

problems.

Skin and body protection : impervious clothing

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures : When using do not eat or drink.

When using do not smoke.

Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : colourless
Odour : vinegar-like
pH : 2.3 - 2.5

Melting point/range : no data available Boiling point/boiling range : no data available

Flash point

does not flash

Flammability (solid, gas) : The product is not flammable.

Upper explosion limit : no data available



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Lower explosion limit : no data available

Solubility(ies)

Water solubility : completely miscible

Auto-ignition temperature : no data available

Thermal decomposition : no data available

Oxidizing properties : The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

: No decomposition if stored and applied as directed.

Conditions to avoid : Heat.

Incompatible materials : Bases

Oxidizing agents

Metals

Hazardous decomposition

products

: Carbon oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate : 31.58 mg/l

Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Components:

acetic acid:

Acute oral toxicity : LD50 Oral rat: 3,310 mg/kg

Acute dermal toxicity : LD50 Dermal rabbit: 1016 µl/kg

Skin corrosion/irritation

Product:



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Remarks: Extremely corrosive and destructive to tissue.

Components:

acetic acid:

Result: Causes severe burns.

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Product:

Remarks: May cause irreversible eye damage.

Components:

acetic acid:

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

no data available

Germ cell mutagenicity

Components:

acetic acid:

Genotoxicity in vitro : Type: Chromosome aberration test in vitro

Method: Mutagenicity (in vitro mammalian cytogenetic test) Remarks: In vitro tests did not show mutagenic effects

Germ cell mutagenicity-

Assessment

: Not mutagenic in Ames Test.

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT - single exposure

Components:

acetic acid:

Remarks: no data available

STOT - repeated exposure

Components:

acetic acid:

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Components:

acetic acid:



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no data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to

the environment

: no data available

Components: acetic acid:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 410 mg/l

Exposure time: 48 h

NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other

aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to

the environment

: no data available

Persistence and degradability

Components:

acetic acid:

Biodegradability : Biodegradation: 71 %

Exposure time: 5 d

Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

Bioaccumulative potential

Components:

acetic acid:

Partition coefficient: n-

octanol/water

: log Pow: -0.31

Mobility in soil

no data available

Other adverse effects



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no data available

Product:

Regulation 40 CFR Protection of Environment; Part 82 Protection of

Stratospheric Ozone - CAA Section 602 Class I Substances This product neither contains, nor was manufactured with a

Remarks

This product neither contains, nor was manufactured with a
Class I or Class II ODS as defined by the U.S. Clean Air Act

Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not contaminate ponds, waterways or ditches with

chemical or used container.

Send to a licensed waste management company.

Can be disposed as waste water, when in compliance with

local regulations.

Contaminated packaging : Empty remaining contents.

Dispose of as unused product.

Empty containers should be taken to an approved waste

handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International regulation

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADNR,

IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION



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OSHA Hazards : Corrosive to skin

WHMIS Classification : E: Corrosive Material

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
A (' ' I	04.40.7	(/	(103)
Acetic acid	64-19-7	5000	

SARA 302 : SARA 302: No chemicals in this material are subject to the

reporting requirements of SARA Title III, Section 302.

SARA 313 : SARA 313: This material does not contain any chemical

components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA

Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

acetic acid 64-19-7 5 %

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

acetic acid 64-19-7 5 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

acetic acid 64-19-7 5 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

acetic acid 64-19-7 5 - 10 %

Pennsylvania Right To Know

water 7732-18-5 90 - 100 % acetic acid 64-19-7 5 - 10 %

New Jersey Right To Know

water 7732-18-5 90 - 100 % acetic acid 64-19-7 5 - 10 %



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California Prop 65

: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

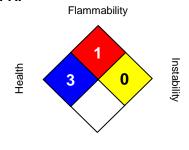
Inventories

AICS (Australia), DSL (Canada), IECSC (China), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIOC (New Zealand), PICCS (Philippines), TSCA (USA)

SECTION 16. OTHER INFORMATION

Further information

NFPA:



Special hazard.

HMIS III:

HEALTH	3
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,

2 = Moderate, 3 = High

4 = Extreme, * = Chronic

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.